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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,423	10/30/2003	Yoseph Yaacobi	1883 B	7191

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EXAMINER	
ROYDS, LESLIE A	
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1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,423	YAACOBI, YOSEPH	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) *2-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/04;4/26/04;2/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 are presented for examination.

Acknowledgement is made of the instant application as a divisional of U.S. Patent Application No. 10/187,006, filed July 1, 2002, now U.S. Patent No. 6,669,950, which is a continuation of U.S. Patent Application No. 09/664,790, filed September 19, 2000, now U.S. Patent No. 6,416,777, which claims benefit under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/160,673, filed October 21, 1999.

Applicant's Information Disclosure Statements (IDS) filed January 30, 2004 (four pages), April 26, 2004 (one page) and February 3, 2005 (one page) have each been received and entered into the present application. As reflected by the attached completed copy of form PTO/SB/08(a-b) (six pages total), the Examiner has considered the cited references.

Applicant's response filed August 14, 2007 to the requirement for restriction/election dated April 6, 2007 has also been received and entered into the present application.

Requirement for Election of Species

Applicant's election of nepafenac as the pharmaceutically active agent for use in the claimed ophthalmic drug delivery device in the reply filed August 14, 2007, is acknowledged by the Examiner. Because Applicant did not distinctly and specifically point out the supposed errors in the requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

Therefore, for the reasons above and those made of record at pages 2-5 of the previous Office Action dated April 6, 2007, the requirement remains proper and is hereby made **FINAL**.

Claims 2-4 are **withdrawn** from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected subject matter.

The claim corresponding to the elected subject matter is claim 1 and this claim is herein acted on

the merits.

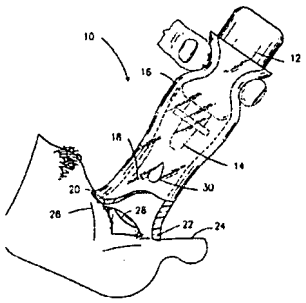
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baron (U.S. Patent No. 5,387,202; 1995) in view of Gamache et al. ("Nepafenac, A Unique Nonsteroidal Prodrug with Potential Utility in the Treatment of Trauma-Induced Ocular Inflammation", *Inflammation*, 2000; 24(4):357-370).

Baron teaches an eye drop dispensing device, comprising a pliable housing having a channel formed therethrough to receive and house the dispensing nozzle and a pliable ophthalmic solution container and an eyelid engaging rim to retain the eyelids in an open conformation to facilitate application of the solution directly to the eye surface (col.2, l.44-51), and further wherein the drops of ophthalmic solution are dispensed into the user's eye by depressing or squeezing the pliable housing that, in turn, squeezes the pliable ophthalmic solution container forcing drops of the solution therefrom, which fall gently onto the surface of the user's eye (col.2, l.52-66). Baron depicts the following device as representative of the disclosed invention:



(Figure 1).

Applicant's claimed "body" of the instant device of the present case is equivalent to the pliable ophthalmic solution container contained within the housing. It has both a "scleral surface" [i.e., the tip of the container, which is placed within the vicinity of (i.e., proximate) to the scleral surface of the user's eye], a well (i.e., the portion of the container that houses the solution), and opening to the scleral surface in the well (i.e., the tip of the container from where the eye drop is dispensed), as well as an "inner core disposed in said well" (i.e., an interior compartment within the larger well itself that houses the ophthalmic solution), which contains the ophthalmic solution (i.e., comprising a pharmaceutically active agent).

Baron fails to teach the specific use of nepafenac as the pharmaceutically active agent for use in the ophthalmic drug delivery device (claim 1).

Gamache et al. is cited for its teachings of the compound nepafenac, a non-steroidal anti-inflammatory compound related to amfenac (abstract), prepared in an ophthalmic vehicle containing 0.5% hydroxypropylmethylcellulose for topical ocular administration (para.1, p.359), which showed significant anti-inflammatory efficacy in treated patients suffering from post-cataract surgery inflammation (para.2, p.368), and suggests its efficacy in treating macular edema post-cataract surgery as a result of its significant anti-inflammatory effect (para.3, p.368).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to include nepafenac into the ophthalmic delivery device of Baron because Baron teaches a means for delivering an ophthalmic solution directly to the eye and Gamache et al. teaches an ophthalmic solution of nepafenac as a potent anti-inflammatory agent effective to reduce excessive ocular inflammation occurring after cataract removal. Such a person would have been motivated to do so by a desire to provide an effective means of administration of the ophthalmic nepafenac solution to an eye in need of treatment of inflammation, pain and/or macular edema, which, in turn, would have facilitated use (and compliance with a prescribed regimen) of the drug by a patient in need of its therapeutic effects.

Furthermore, it is noted that the delivery device of Baron would have been necessarily capable of delivering any known ophthalmic preparation to the eye, particularly nepafenac, due to the physical structure of the device, which imparts the ability to dispense measured drops of an ophthalmic solution, and its amenability for use proximate to the eye surface, absent factual evidence to the contrary.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 17-19 of U.S. Patent No. 6,416,777.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited copending application are not considered patentably distinct from each other because the pending claims are anticipated by the patented claims.

The patented claims clearly provide for a drug delivery device for a human eye (i.e., ophthalmic), wherein the device comprises a body having a scleral surface for placement proximate an outer surface of

the sclera and a well having an opening to said scleral surface and an inner core disposed in said well that comprises a pharmaceutically active agent. The patented claims further comprise embodiments of the device wherein the active agent is nepafenac.

Accordingly, rejection of claim 1 is proper over claims 1-14 and 17-19 of copending U.S. Patent No. 6,416,777 as claiming obvious and unpatentable variants thereof.

Claim 1 is provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over, alternatively, claims 15-20 of copending U.S. Patent Application No. 11/248,727 or claims 1-5 of copending U.S. Patent Application No. 11/567,892, or is rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-5, 11 and 18 of U.S. Patent No. 6,808,719, each in view of Gamache et al. ("Nepafenac, A Unique Nonsteroidal Prodrug with Potential Utility in the Treatment of Trauma-Induced Ocular Inflammation", *Inflammation*, 2000; 24(4):357-370).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited copending application are not considered patentably distinct from each other because the pending claims are obvious over the copending or patented claims.

The patented claims of the '719 patent and the copending claims of the '727 application clearly provide for a drug delivery device for a human eye (i.e., ophthalmic), wherein the device comprises a body having a scleral surface for placement proximate an outer surface of the sclera and a well having an opening to said scleral surface and an inner core disposed in said well that comprises a pharmaceutically

active agent. The patented claims further provide for the use of, specifically, a non-steroidal anti-inflammatory agent or an agent effective for the treatment of macular edema (see, e.g., patented claims 11 and 18).

The copending claims of the '892 application provide for a substantially identical device but fail to state that the device is for ophthalmic use as instantly claimed. However, such a limitation is an intended use of the device and fails to be a patentable distinction between the copending claims and the instant claims because it fails to impart any physical or material property to the instant device that is not already present in the device of the copending claims.

Though the copending claims provide for the inclusion of a pharmaceutically active agent in the inner core of the device, but fail to specifically recite the use of nepafenac as the active agent, Gamache et al. is cited for its teaching of nepafenac as an effective non-steroidal anti-inflammatory agent useful for the treatment of ocular pain, inflammation and macular edema (abstract, para.2, p.368 and para. bridging p.368-369). One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to include an agent, such as, e.g., nepafenac, into the drug delivery device(s) of the copending claims. Such a person would have been motivated to do so by a desire to provide a effective means of administration of the ophthalmic solution to an eye in need of treatment of inflammation, pain and/or macular edema, which, in turn, would have facilitated use, and compliance with a prescribed regimen, of the drug by a patient in need of its therapeutic effects. Furthermore, it is noted that the patented or copending delivery device would have been fully capable of delivering any known ophthalmic preparation to the eye, including nepafenac, due to its physical structure and amenability for use proximate to (or even in contact with) the eye surface, absent factual evidence to the contrary.

Accordingly, rejection of claim 1 is proper over claims 15-20 of copending U.S. Patent Application No. 11/248,727 or claims 1-5 of copending U.S. Patent Application No. 11/567,892 or claims 4-5, 11 and 18 of U.S. Patent No. 6,808,719 as claiming obvious and unpatentable variants thereof.

Claim 1 is provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending U.S. Patent Application No. 10/957,910, or is rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,413,540, each in view of Gamache et al. ("Nepafenac, A Unique Nonsteroidal Prodrug with Potential Utility in the Treatment of Trauma-Induced Ocular Inflammation", *Inflammation*, 2000; 24(4):357-370).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited copending application are not considered patentably distinct from each other because the pending claims are obvious over the copending or patented claims.

The patented claims of the '540 patent and the copending claims of the '910 application clearly provide for a drug delivery device for a human eye (i.e., ophthalmic), wherein the device comprises a body having a scleral surface for placement proximate to (or in contact with) an outer surface of the sclera and a well having an opening to said scleral surface and an inner core disposed in said well that comprises a pharmaceutically active agent. Both the patented claims and the copending claims further provide for the use of, specifically, a steroid (i.e., 4,9(11)-pregnadien-17alpha,21-diol-3,20-dione or 4,9(11)-pregandien-17alpha,21-diol-3,20-dione-21-acetate) or eliprodil as the active agent (see, e.g., patented claims 1-2 and copending claims 12-13).

Though the copending claims provide for the inclusion of a pharmaceutically active agent in the inner core of the device, but fail to specifically recite the use of nepafenac as the active agent, Gamache et al. is cited for its teaching of nepafenac as an effective non-steroidal anti-inflammatory agent useful for

the treatment of ocular pain, inflammation and macular edema (abstract, para.2, p.368 and para. bridging p.368-369). One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to include and/or substitute an agent, such as, e.g., nepafenac, into the drug delivery device(s) of the patented or copending claims. Such a person would have been motivated to do so by a desire to provide a effective means of administration of the ophthalmic solution to an eye in need of treatment of inflammation, pain and/or macular edema, which, in turn, would have facilitated use, and compliance with a prescribed regimen, of the drug by a patient in need of its therapeutic effects. Furthermore, it is noted that the patented or copending delivery device would have been fully capable of delivering any known ophthalmic preparation to the eye, including nepafenac, due to its physical structure and amenability for use proximate to (or even in contact with) the eye surface, absent factual evidence to the contrary.

Accordingly, rejection of claim 1 is proper over claims 1-13 of copending U.S. Patent Application No. 10/957,910 or claims 1-2 of U.S. Patent No. 6,413,540 as claiming obvious and unpatentable variants thereof. This is a provisional rejection because the claims have not yet, in fact, been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent No. 5,848,999 to Basilice et al. ("Dispensing Eye Drops") and U.S. Patent No. 3,756,478 to Podell et al. ("Eye Drop Dispenser with Liquid Metering Device").

Rejection of claim 1 is proper.

Claims 2-4 are **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

October 19, 2007

Ardin H. Marschel 10/21/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER